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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,093	12/06/2004	Frank Seibertz	RO0953US(#90568)	1122

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,093	SEIBERTZ ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) *7-10,24-41 and 47-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 11-23, 42-46 and 83-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed May 5, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-6, 11-23, 42-46 and 83-90 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McGinity et al. (US 2001/0006677) in view of Zerbe et al. (US 6,177,096). The rejection withdrawn in regard to claims 6, 11-19, 42-46 and 87-90.

Applicant's Arguments

The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider McGinity, et al. alone, or in combination with the cited secondary reference, each and

every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered as the prior art teaches away. McGinity, et al. fail to teach the limitation of amended claim 6. In addition, McGinity, et al. do not teach or disclose to dissolve or suspend water-soluble polymers and gas- forming components in a solvent, spreading a composition comprising both water-soluble polymers and gas-forming components, and drying the composition. McGinity, et al. use a completely different technology, i.e., a hot- melt extrusion, to prepare effervescent controlled release water soluble films. In contrast the process of the presently claimed invention recites the preparation of films using solvent-based technologies. It is further submitted that since the reference of McGinity, et al. is related to a completely different technology for preparing effervescent controlled release water soluble films, the reference would not be referenced by one skilled in the art to arrive at the presently claimed invention. In particular, reference to McGinity, et al. by one skilled in the art regarding the present invention would render the presently claimed invention inoperable. This is particularly true since the disclosure of McGinity, et al. teaches away from the presently claimed invention in that McGinity, et al. teach that the process described therein does not require the use of solvents (emphasis added) in order to avoid disadvantages, such as longer exposure times of components to elevated temperatures. Zerbe, et al. (and Young, et al.) fail to make up for any of the numerous deficiencies of McGinity, et al. and thus the combination of teachings of the references would not teach each and every limitation of the presently

claimed invention.

Examiner's Response

The Examiner disagrees and submits that McGinity et al. disclose the procedures encompassed do not require solvents, it does not disclose that solvents cannot be used. Nor does it disclose there are disadvantages in using a solvent, especially considering the polymers used to make the films may be in non-aqueous solvents. Thus, when using these polymers, the limitation of "dissolving or suspending the components in a solvent" is met. In regard to spreading said coating compound on a support, when extruding the composition, it is reasonable to conclude that the composition is extruded on a surface in order to form the film, thereby meeting this limitation. In regard to the drying step recited in the instant claims, it is reasonable for one of skill in the art to dry the extruded films in order to remove the non-aqueous solvents or co-solvents to make a dry film. Therefore McGinity et al. does not teach away from the instant claims.

Additionally, as previously submitted, McGinity et al. disclose that certain hot melt procedures degrade the actives. In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to make films using a method that does not degrade the extruded materials. Accordingly, it would have been obvious

to one of ordinary skill in the art to look to other methods in order to avoid this. Therefore it would have been obvious to use the methods of Zerbe et al. to make the films of McGinity et al., especially when non-aqueous solvents are used. Thus it is believed that McGinity et al. teaches non-aqueous solvents and McGinity itself further supports why one of ordinary skill in the art would want to explore other methods of forming the films.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 6, 11-19, 42-46 and 87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinity et al. (US 2001/0006677) in view of Bettman et al. (US 5,639,475)

The reference has been discussed in detail in the Office Action mailed November 14, 2008. The reference differs from the instant claims insofar as it does not disclose that the gas forming components are present in microencapsulated form.

Bettman et al. disclose effervescent microcapsules. The microcapsules comprise an effervescent mixture of citric acid and sodium bicarbonate. The effervescent microcapsules are useful in formulating taste masked effervescent chewable tablets also containing microencapsulated, unpleasant tasting drugs such as non-steroidal, anti-inflammatory, NSAID drugs (Abstract). The taste masked effervescent microcapsules maintain a controlled effervescent reaction in the mouth without a "burst" effect. Also the effervescent microcapsules provide increased product stability and less

need for humidity control during processing, for example, manufacture on a conventional tablet press (col. 2, lines 18-26).

The reference differs from the instant claims insofar as it does not disclose the preparation is a film.

It would have been obvious to one of ordinary skill in the art to have microencapsulated the effervescent mixture of McGinity et al. motivated by the desire to mask the unpleasant taste, maintain a controlled effervescent reaction in the mouth without a "burst" effect and provide increased product stability and less need for humidity control during processing of the mixture as disclosed by Bettman et al.

Claims 1-6, 11-23, 42-46 and 83-90 are rejected.

Claims 7-10, 24-41 and 47-82 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612